

DETAILED ACTION

Response to Arguments and amendments

1. The response filed on 2/5/10 has been entered.
2. Applicant's arguments filed 2/5/10 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 18-20, 24-29, 31-32, 34 and 36 are pending in this office action. Claims
5. The rejection of claims 18-20, 24-29, 31-32, 34 and 36 under 35 U.S.C. 112, first paragraph, for new matter rejection as it relates to HEC and CMC is withdrawn based on the amendment to the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-20, 24-29, 31-32, 34 and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable Over Lawlor (US 6,706,256) for the reasons made of record in Paper No: 20091106 and as follows.

Applicant argues that "[t]o establish a *prima facie* case of obviousness under §103, the Examiner has the burden of showing, by reasoning or evidence, that: 1) there is some suggestion or motivation, either in the references themselves or in the knowledge available in the art, to modify that reference's teachings; 2) there is a reasonable expectation on the part of one of ordinary skill in the art that the modification or combination has a reasonable expectation of success; and 3) the prior art references (or references when combined) teach or suggest all the claim limitations. MPEP §2145.

Applicants submit that the burden of a *prima facie* case of obviousness has not been met". Applicant also argues that "...the present claim limitations that the composition forms an intact hydrated mass that is visible on 2 to 3 molar or premolar surfaces to greater than 7 molar or premolar surfaces for 5 minutes to 60 minutes after a human subject chews two tablets of the composition for 5 to 30 seconds, brushes his or her teeth with a manual, flat head, soft toothbrush for 30 seconds, expectorates the slurry created from the brushing, and then rinses with 10 ml of water and expectorates again is not taught or remotely suggested by the cited references".

In Response obviousness under 103(a) requires the showing of:

Determining the scope and contents of the prior art: in this instant as it now relates to the amended claims Lawlor teaches an oral care formulation (dentifrice) comprising of hydroxyethyl cellulose (HEC) and water soluble salts of cellulose such as carboxymethyl cellulose (CMC) in the amount of 0.1%-15% (as it relates to instant claims 18, 28, 32 and 34; see col. 21, lines 45-56). The preamble "the retentive agent having a property of hydrating upon exposure to water or saliva alternatively is a function or a property of the retentive agent HEC and CMC (see MPEP 2112.01).

Claim 18 (item b) requires a flavor or an abrasive or a buffer etc. Lawlor teaches flavoring agents, and abrasives (as required by instant claim 18(b); see col. 18, lines 1-10). Lawlor also teaches the composition comprises additional agents such as H-2 antagonists, anticalculus, fluoride ions (as required by instant claims 24 and 25; see col. 9, lines 59-67) in a compressed tablet (as required by instant claim 26; see col. 15, lines 46-48). With the limitation of wherein the composition is non-effervescent, it is anticipated that chewing gum and hard candies are non-effervescent, thus the limitation of instant claims 26-27 and 31 is met. Lawlor further teaches the oral composition comprises a buffering agent wherein the buffering agents have a pH of 3-10. Therefore when chewed the composition will buffer the oral cavity within the recited claimed limitations (as required by instant claims 28-29, see col. 22, lines 1-16). Lawlor teaches inclusion of polyethylene wax (an insoluble polymer) in an amount of 5-20%, see col. 16, lines 34-48 as required by instant claim 18c for example)

Ascertaining the differences between the prior art and the claims at issue

Lawlor fails to specifically teach item (d) in claims 28, 32 and 36. Lawlor is also silent on the teaching of the composition forms an intact hydrated mass that is visible on 2 to 3 molar or premolar surfaces to greater than 7 molar or premolar surfaces for 5 minutes to 60 minutes after a human subject chews two tablets of the composition for 5 to 30 seconds, brushes his or her teeth with a manual, flat head, soft toothbrush for 30 seconds". Lawlor also fails to teach the specific combinations of a retentive agent as 7% HEC and about 6% CMC (as required by instant claim 36).

Resolving the level of ordinary skill in the pertinent art.

La Rochelle teaches a soft chewable lozenge that may comprise water-soluble ingredients combined with water insoluble polishing agents such as starch adhesive that permits degree of coating (i.e., high amylase corn, which is known in the art to comprise pectin (absent factual evidence to the contrary, see col. 3, lines 15-42 and col. 4, lines 43-60). La Rochelle also teaches that when these lozenges are chewed they form a sticky mass on the tooth surface (see col. 5, line 10-15) and further cleaning the teeth involves chewing these lozenges and intrinsically the participation of a tooth brush is involved when the teeth are being cleaned (see col. 5, lines 19-23).

However La Rochelle fails to teach the specific retentive agents as CMC and HEC as required by instant claim 18a for example.

Considering objective evidence present in the application indicating obviousness or nonobviousness

One of ordinary skill in the art would have been motivated to expand Lawlor's composition to La Rochelle composition which teaches that when these lozenges are

chewed they form a sticky mass on the tooth surface (see col. 5, line 10-15) and further cleaning the teeth involves chewing these lozenges. Intrinsically the non-cariogenic, chewable solid unit dosage form composition will form an intact hydrated mass that is visible on 2 to 3 molar or premolar surfaces to greater than 7 molar or premolar surfaces for 5 minutes to 60 minutes after a human subject chews two tablets of the composition for 5 to 30 seconds, brushes his or her teeth with a manual, flat head, soft toothbrush for 30 seconds as required by the claims.

Also Applicant should note that even though the Examiner has taken the time to meet the recited limitation, it does not have any patentable weight because a composition is a composition and it's intended use is given no patentable weight. "A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone". See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

One of ordinary skill in the art would have been motivated to substitute either Lawler's insoluble polyethylene wax for La-Rochelle's high amylase-corn to effectively result in a higher degree of coating to allow the composition to stick on to the teeth upon when chewed in the ranges taught by Lawlor because concentration of the active ingredient is a result-effective variable (i.e., a variable that achieves a recognized result) and, therefore, the determination of the optimum or workable dosage range would have

been well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Therefore the combination of Lawlor and La Rochelle makes the claim invention obvious to one of ordinary skill in the art at the time the claimed invention was made.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
4/6/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649